

Claims listing:

1. (original) A device, for use in a metering device for measuring analyte levels in a sample fluid, said device comprising: a cartridge; a plurality of analyte detecting members mounted on said cartridge, said detecting members using an optical technique to measure analyte levels in said sample fluid.
2. (original) The device of claim 1 wherein said cartridge does not include any penetrating members.
3. (original) The device of claim 1 wherein said cartridge has a radial disc shape.
4. (original) The device of claim 1 wherein said cartridge is sized to fit within said metering device.
5. (original) The device of claim 1 wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing materials.
6. (original) The device of claim 1 wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing materials deposited in a single step.
7. (original) The device of claim 1 wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing materials; the emulsion is one selected from the following group: emulsifiers with liquid silicone/hydrogel system, emulsifiers with x-linked silicone/hydrogel system, emulsifiers of siloxane sol-gel/hydrogel system, TERGITOL TMN series of emulsifiers, and mixtures thereof.
8. (original) The device of claim 1 wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing

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materials; the emulsion having a desired HLB for polydimethylsiloxane (PDMS) silicone oil of 9- 11.

9. (original) The device of claim 1 wherein the analyte detecting member comprises natural pyrroloquiniline quinone (PQQ) and used in conjunction with an autoxidisable electron acceptor.

10. (original) The device of claim 1 wherein the analyte detecting member comprises natural pyrroloquiniline quinone (PQQ) and used in conjunction with an autoxidisable electron acceptor such as phenazine methosulphate (PMS) or phenazine ethosulphate (PES).

11. (original) The device of claim 1 wherein the analyte detecting member comprises a block copolymer of hydrophobic and hydrophilic polymers such as polydimethylsiloxane (PDMS) or poly (ethylene oxide) (PEO).

12. (original) The device of claim 1 wherein the analyte detecting member wherein an emulsion particle size is sufficiently small that it is geometrically impossible for a GOX molecule to fit inside it.

13. (original) The device of claim 1 wherein the analyte detecting member comprises a block copolymer of hydrophobic and hydrophilic polymers such as polydimethylsiloxane (PDMS) or poly (ethylene oxide) (PEO), wherein PEO chains are cross-linked.

14. (original) The device of claim 1 wherein the analyte detecting member comprises an emulsion of Ru sensing phase within a group of oxidase sensing materials, said emulsion containing 1: 2 (v/v) hydrophobic/hydrophilic phases, 4: 1 (w/w) Monomer 5 : Monomer 1 mixture for the hydrophobic phase and 1 mg/mL GOX content in the hydrophilic phase.

15. (original) The device of claim 1 wherein the cartridge includes a plurality of wells and a central fluid input port for receiving a body fluid with one or more analytes,

said plurality of wells coupled to the common input port, each of said wells equidistant to the input port.

16. (original) The device of claim 1 wherein the cartridge includes a plurality of wells and a central fluid input port for receiving a body fluid with one or more analytes, said plurality of wells coupled to the common input port, each of said wells equidistant to the input port, said wells positioned to have a star configuration.

17. (original) The device of claim 1 wherein said analyte detecting members have different sensitivity ranges enhancing the overall range of sensitivity of an array of such members when used on a single fluid sample.

18. (original) The device of claim 1 wherein said analyte detecting members can provide their analysis requiring no more than one of the following volumes: 300,200, 100,60, 50,30, 20,15, 10, and 5 nanoliters.

19. (original) The device of claim 1 further comprising a mesh configured fluid spreader positioned over said analyte detecting member.

20. (original) The device of claim 1 wherein the cartridge has a higher density of analyte detecting members than 4.53 cubic centimeters divided by 17 per single analyte detecting member.

21. (original) The device of claim 1 wherein the cartridge has a higher density of analyte detecting members than 4.53 cubic centimeters divided by 20 per single analyte detecting member.

22. (original) The device of claim 1 wherein the cartridge has a higher density of analyte detecting members than 4.53 cubic centimeters divided by 25 per single analyte detecting member.

23. (original) The device of claim 1 wherein the cartridge has a higher density of analyte detecting members than 4.53 cubic centimeters divided by 50 per single analyte detecting member.

24. (currently amended) A device for use with a body fluid sampling device for extracting bodily fluid from an anatomical feature, said device comprising: a cartridge having a plurality of sample chambers; a plurality of analyte detecting members using an optical technique to measure analyte levels in a sample fluid; wherein at least one of said analyte detecting members forms a portion of one wall of one of said plurality of sample chambers; said analyte detecting members using an optical technique to determine analyte level in the body fluid.

25. (currently amended) The device of claim 12 24 wherein said cartridge further comprises a plurality of penetrating member in cavities on said cartridge.

26. (canceled).

27. (currently amended) The device of claim 19 26 wherein said fluid path contains a channel sized to hold no more than 1 microliter.

28. (original) A method for determining a concentration of an analyte in body fluid, comprising: collecting a sample of body fluid of about 500 nL or less; covering an electrochemical sensor with at least a portion of the sample; determining the concentration of the analyte in the sample using a optical technique.

29. (original) A method for manufacturing a device, the method comprising: providing a cartridge having a plurality of wells; depositing an emulsion in the wells; scraping away emulsion from tops of the wells, in order to level the amount of emulsion in each well.

30. (canceled).

31. (canceled).

32. (currently amended) A system comprising: a single cartridge having a plurality of cavities; a plurality of analyte detecting members on the single cartridge using an optical technique to measure analyte levels in a sample fluid; a memory on said device for storing at least one of the following: number of penetrating members

used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members.

33. (currently amended) A system comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members using an optical technique to measure analyte levels in a sample fluid; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue

relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members.

34. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; an

optical train for directing reflected light from the analyte detecting member to an optical detector.

35. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; an optical train for directing reflected light from the analyte detecting member to a CMOS optical detector, said CMOS optical detector is utilized to measure fluorescence lifetimes of the analyte detecting members, wherein a time dependent optical image can be sampled and integrated, on the CMOS by a processor in the system.

36. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to

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penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; an optical train for directing reflected light from the analyte detecting member to an optical detector; a grating for displacing an excitation image and a fluorescence image from the analyte detecting member.

37. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating

member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; a process using spectral encoding techniques to spectrally slice the fluorescence spectrum of multiple wells and complementary spectral filtering in the filter plane, to separate out the light from the wells to make image position insensitive to the well positions.

38. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed

profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; a diffuser in the optical train guiding light from the wells to the light detector.

39. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; a movable viewing lens to correct of misalignment of detector and the object illuminated.

40. (currently amended) A The system of claim 33 further comprising: an electric penetrating member driver; a single cartridge having a plurality of cavities; a plurality of penetrating members housed in said cavities and individually movable by said driver to penetrate tissue; a plurality of analyte detecting members; a memory on said device for storing at least one of the following: number of penetrating members used, number of target tissue penetrating events, time and date of the last selected number of target tissue penetrating events, time interval between alarm and target tissue penetrating event, stratum corneum thickness, time of day, energy consumed by a penetrating member driver to drive a penetrating member into the target tissue, depth of penetrating member penetration, velocity of the penetrating member, desired velocity profile, velocity of the penetrating member into the target tissue, velocity of the penetrating member out of the target tissue, dwell time of the penetrating member in the target tissue, a target tissue relaxation parameter, force delivered on the target tissue, dwell time of the penetrating member, battery status, system status, consumed energy, speed profile of the penetrating member as the penetrating penetrates and advances through the target tissue, a tissue target tissue relaxation parameter, information relative to contact of a penetrating member with target tissue before penetration by the penetrating member, information relative to a change of speed of a penetrating member as it travels in the target tissue, type of electrochemical analyte detecting member used, the kind of test the analyte detecting member will be measuring, information relative to consumed sensors and/or information relative to consumed penetrating members; a slurry laid over a well of the analyte detecting member ; a plurality of luminescent beads of the same color with different non- overlapping lifetimes ranges for their particular analyte, said beads in said slurry.